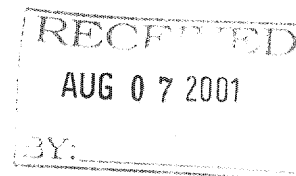


BIOCODEX Inc.

1910 Fairview Avenue East, Suite 208
Seattle, Washington 98102-9530

July 30th, 2001



VIA COURIER

JV/ME/001-01

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

RE: New dietary supplement: ORNIDEX™

Dear CFSAN,

Enclosed please find an original and two copies of "Notification of Marketing Dietary Supplement" submitted pursuant to section 101.93 of the Federal Food, Drug and Cosmetic Act, on behalf of Biocodex, Inc.

Thank you for your attention to this matter. If you have any questions relating to the notification, please do not hesitate to call our offices in Creswell, Oregon at: 1-541-895-8910.

97S 0162

LET 8450

July 30th, 2001

Notification of the Marketing of a new Dietary Supplement

ORNIDEX™

Pursuant to section 21CFR101.93 of the Federal Food, Drug, and Cosmetic Act, Biocodex, Inc., located at 300 North Mill street, Unit A, Creswell, Oregon 97426, hereby notifies the Food and Drug Administration that it has marketed the new dietary supplement, ORNIDEX™, on July 24th, 2001. ORNIDEX™ is an encapsulated powder of ornithine.

I. Dietary Supplements containing ornithine

Biocodex, Inc. will market ORNIDEX™ for use in dietary supplements at a level of 1 800 mg/day. The labeling of ORNIDEX™ states that ORNIDEX™ facilitates protein synthesis and reestablishes an optimum nitrogen balance between protein synthesis and degradation.

II. Evidence of Safety

ORNIDEX™, when used under the conditions recommended in the indicated labeling, is reasonably expected to be safe. The active ingredient, ornithine, is referenced in the Martindale (32d ed). It has been used in several countries for over 15 years at equivalent or higher oral dose levels with excellent tolerance profile ⁽¹⁾⁽²⁾.

III. Manufacturer

ORNIDEX™ is manufactured and packaged by Laboratoires Biocodex, 1 Avenue Blaise Pascal, Beauvais, Oise, FRANCE. ORNIDEX™ is imported and distributed by Biocodex, Inc., 300 North Mill street, Unit A, Creswell, Oregon 97426.

IV. Health Claim

The label on ORNIDEX™ states that it "facilitates protein synthesis" and "reestablishes an optimum nitrogen balance". No claims to diagnosis, treat, cure or prevent any disease is made.

¹ P. Brocker et al. A two-center, randomized, double blind trial of ornithine oxoglutarate in 194 elderly ambulatory convalescent subjects.
Age and Ageing 1994; 23 (4): 303-306.

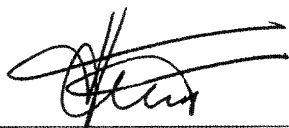
² G. Debry, T. Poynard
Value of ornithine alpha-ketoglutarate of nutritional support in convalescent, malnourished elderly subjects.
Facts and research in Gerontology: focus on long term care
Bruno J Vellas ed. Springer 1995.

V. Active Ingredient

The active ingredient of ORNIDEX™ is ornithine. No other dietary ingredient is contained in the supplement.

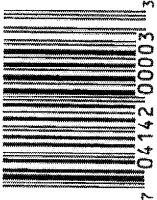
VI. Responsible Party


Pursuant to section 21CFR101.93(c) of the Federal Food, Drug, and Cosmetic Act, I, the undersigned, certify that the information contained in the notice is complete and accurate, and that Biocodex, Inc. has substantiation that the above statements are truthful and not misleading.

A handwritten signature in black ink, appearing to read 'François Hublot', is written over a horizontal line.

François Hublot
President

Enclosures: Panels from the ORNIDEX™ product container.






Ornidex™

Ornithine from Biocodex

Amino Acid Dietary Supplement



MADE IN FRANCE BY A PHARMACEUTICAL LABORATORY

60 CAPSULES

DO NOT USE IF SEAL IS BROKEN

Enhance your muscular capacity with Ornidex™

If you know that your nutrition needs improvement®...

Ornidex™

➤ **Provides ornithine,** which is a pure and natural amino acid. This supplement of ornithine facilitates protein synthesis and reestablishes an optimum nitrogen balance between protein synthesis and degradation.

➤ **Provides nutritional value.** With aging or a sedentary lifestyle, intake of key nutrients does not meet body needs resulting to unrecognized undernutrition. Ornithine, the active ingredient of Ornidex™, elevates levels of amino acids and enhances body protein composition resulting in increased muscular capacity.

Statements on this package have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Manufactured by Laboratoires Biocodex, France
Imported by Biocodex, Inc., Seattle, WA

Supplement Facts

Serving Size : 2 Capsules	
Servings per Container : 30	
Amount per Capsule :	
L-Ornithine	300 mg*
*Daily Value (DV) not established	

Other ingredients : Dibasic Calcium Phosphate, Colloidal Silica, Magnesium Stearate, Hydroxypropyl-methyl-cellulose, Titanium Dioxide (E 171)

Directions for use :

Take 2 capsules, 3 times per day, for 10 days.

For product information contact :

Biocodex, Inc.
300 North Mill Street
Creswell, OR 97426
www.ornidex.com